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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,898	11/28/2001	Scott R. Presnell	00-108	1509

7590 07/17/2003

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EXAMINER
KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
1646	8

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,898	PRESNELL ET AL.	
	Examin r	Art Unit	
	Claire M. Kaufman	1646	

-- Th MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 22 and 24, drawn to polynucleotide, vector, host cell and method of expressing polynucleotide, classified in class 536, subclass 23.1 and class 435, subclass 69.1.

*II. Claims 17-21 and 23, drawn to polypeptide, classified in class 530, subclass 350.

III. Claims 25-29, drawn to antibody and method of producing the antibody, classified in class 530, subclass 388.22 and class 424, subclass 185.1.

IV. Claim 30, drawn to method of detecting presence of activity modulator of a cytokine receptor, classified in class 435, subclass 7.2.

V. Claims 31-33, drawn to method of detecting a cytokine receptor ligand, classified in class 436, subclass 501.

VI. Claim 34, drawn to method of detecting a genetic abnormality with nucleic acid protein hybridization followed by reaction product visualization, classified in class 536, subclass 24.31.

VII. Claim 35, drawn to method of detecting cancer with an antibody, classified in class 435, subclass 7.1.

VIII. Claim 36, drawn to method of detecting cancer with a nucleic acid hybridization probe for polynucleotide level comparison, classified in class 435, subclass 6.

*Note that in claim 21, the third word appears to be a typographical error presenting "polynucleotide" where "polypeptide" should be. As a result, claim 21 as been assigned to Invention II. If this is incorrect, Applicants should correct antecedent basis for polynucleotide and indicate to which group the claim properly belongs.

The inventions are distinct, each from the other because of the following reasons:

The polynucleotide of Invention I is related to the polypeptide of Invention II by virtue of encoding the same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell, as recited in claim 22. Although the polynucleotide and polypeptide

are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthesis or purification from the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as nucleic acid hybridization assay.

Inventions I and III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions cannot be used together since the methods of Inventions III and VII require an antibody not a polynucleotide and the antibody is not encoded by the polynucleotide. The polynucleotide has a different function than the antibody, that is, encoding the polypeptide which is the cognate antigen of the antibody.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide may be used for a materially different process other than expression of the encoded protein, for example, in a hybridization assay for detection of structurally related polynucleotides from other species or for *in situ* hybridization localization.

Invention I is related to Inventions VI and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide may be used for a materially different process other than expression of the encoded protein, for example, in a hybridization assay for detection of structurally related polynucleotides from other species or for *in situ* hybridization localization.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the method of Invention V does not use the polynucleotide of Invention I and, therefore, the polynucleotide and method have different functions or effects.

The polypeptide of Invention II is related to the antibody of Invention III of by virtue of being the cognate antigen, necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because the polypeptide can be used for another and materially different process other than for production of the antibody, such as to assay or purify the natural ligand of the polypeptide (as the polypeptide is asserted to be a receptor), or in assays for the identification of natural binding partner of the polypeptide.

Invention II is related to Inventions III and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in another materially different process such as in the purification of a natural binding partner.

Invention II is unrelated to Inventions VI and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together because the methods of Inventions VI and VIII require a polynucleotide instead of a polypeptide and the polypeptide has a different mode of operation such that hybridization with a polynucleotide cannot occur, also a change in polynucleotide level or structure does not necessary produce a corresponding change in the encoded polypeptide level or structure.

Inventions II and IV-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in a materially different process such as in the production of an antibody.

The methods of Inventions III-VIII are each unrelated one from another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each method has a different mode of operation requiring different method steps and different functions: detection of the presence of an activity modulator of a cytokine receptor, detection of a cytokine receptor ligand, detection of a genetic abnormality, detection of cancer with an antibody, and detection of cancer with a nucleic acid probe, respectively.

Invention III is related to Invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for another materially different process such as in the immunocytochemical tissue localization of the receptor.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, have recognized divergent subject matter, and because each invention requires a separate non-coextensive search, restriction for examination purposes as indicated is proper.A telephone call was made to Deborah A. Sawislak on July 15, 2003, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

July 17, 2003